IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Randolph J. Noelle et al.

Application No.: 09/835,126 | Confirmation No.: 4674

Filed: April 16, 2001 | Art Unit: 1644

For: *EX VIVO* TREATMENT OF ALLOGENEIC AND XENOGENEIC DONOR T-CELLS CONTAINING COMPOSITIONS (BONE MARROW) USING gp39 ANTAGONISTS AND USE THEREOF | Examiner: P. Gambel

SUBSTITUTE "SUMMARY OF CLAIMED SUBJECT MATTER" SECTION TO APPEAL BRIEF FILED OCTOBER 3, 2006

Mail Stop: Appeal Brief Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 41.37(c)(1)(V) and the Order Returning the Undocketed Appeal to the Examiner, this paper provides a summary of the claimed subject matter mapped to the specification, and should be substituted for the content under the heading "**SUMMARY OF CLAIMED SUBJECT MATTER**" contained in the Appeal Brief dated October 3, 2006.

V. Summary of claimed subject matter

The presently claimed invention (as set forth in independent claim 1) provides for a method of inducing T-cell tolerance or non-responsiveness of donor T-cells to desired alloantigen-bearing cells *ex vivo* comprising six steps (specification, Abstract; page 1, lines 15-18; page 4, lines 12-19; page 6, lines 22-26; page 8, lines 6-9; page 9, lines 13-22). These six steps are: (i) purifying $CD4^+$ T-cells from donor tissue (specification, page 8, lines 22-23; Example 1, page 10, lines 28-30); (ii) irradiating alloantigen-bearing cells obtained from a recipient to deplete recipient T-cells (specification, page 8, lines 23-24; Example 1, page 10, line 30 – page 11, line 1); (iii) producing a mixed lymphocyte reaction culture comprising the purified donor $CD4^+$ T-cells and irradiated, T-cell-depleted alloantigen-bearing cells obtained from the recipient (specification, page 4, lines 28-30; page 7, lines 6-8; page 8, lines 6-9 and lines 22-24; Example 1, page 10, line 26 – page 11, line 1); (iv) adding an anti-gp39 antibody to the culture, thereby initiating a mixed lymphocyte reaction culture comprising purified donor $CD4^+$ T-cells, T-cell depleted recipient alloantigen-bearing cells, and an anti-gp39 antibody (specification, page 4, lines 24-25; page 4, line 30 – page 5, line 1; page 7, lines 6-10; page 8, lines 24-27; Example 1, page 10, line 26 – page 11, line 3; Figure 1); (v) maintaining the mixed lymphocyte reaction culture *ex vivo* for a sufficient time to render the donor $CD4^+$ T-cells substantially tolerant or non-responsive to said alloantigen-bearing cells (specification, page 4, lines 24-27; page 8, lines 27-29; Example 4, page 12, lines 1-5; Table 1); and (vi) assaying *ex vivo* for induction of donor $CD4^+$ T-cell tolerance or non-responsiveness (specification, page 9, lines 1-2; Examples 1-7, page 10, line 26 – page 13, line 10; Figures 1-4).

In step (v), the donor T-cells can be cultured for 5 to 30 days as recited in claim 6 (specification, page 8, lines 28-29; Example 4, page 12, line 2; Table 1) or from 6 to 10 days as recited in claim 7 (specification, page 8, lines 28-29; Example 4, page 12, line 2; Table 1).

When treated with this method, transplanted donor tissue does not cause a Graft Versus Host Disease (GVHD) response that might otherwise occur upon transplantation of donor tissues into a recipient (specification, page 4, lines 20-24; Examples 8-10, page 13, line 12 – page 14, line 29; Figures 5A and 5B).

It is respectfully submitted that the Appeal Brief filed October 3, 2006 now fully meets the requirements of 37 C.F.R. § 41.37 and the application is ready to be docketed for appeal.

Dated: June 6, 2007

Respectfully submitted,

By _____

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